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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION
10/824,563	04/15/2004	Henriette Gourdeau	PHARMA 100 D2	6418
24999	7590 06/02/2006		EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, PC			ANDERSON, JAMES D	
2200 CLARI	ENDON BLVD			
SUITE 1400			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22201			1614	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/824,563	GOURDEAU ET A	AL.			
	Office Action Summary	Examiner	Art Unit				
		James D. Anderson	1614				
Dorind	The MAILING DATE of this communication	appears on the cover sheet	with the correspondence ad	dress			
	for Reply	DLV IS SET TO EVOIDE 4	MONTU(S) OD TUIDTV (2	0) DAVS			
WH - Ex aft - If N - Fa An	HORTENED STATUTORY PERIOD FOR REICHEVER IS LONGER, FROM THE MAILING tensions of time may be available under the provisions of 37 CFR or SIX (6) MONTHS from the mailing date of this communication. To period for reply is specified above, the maximum statutory per liture to reply within the set or extended period for reply will, by stay reply received by the Office later than three months after the marked patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUN R 1.136(a). In no event, however, may riod will apply and will expire SIX (6) Mo atute, cause the application to become	IICATION. a reply be timely filed ONTHS from the mailing date of this ABANDONED (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed on 15	5 April 2004.					
•	<u> </u>	This action is non-final.					
3)[_						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispos	ition of Claims						
4)⊠	• 4)⊠ Claim(s) <u>11-50</u> is/are pending in the application.						
,_	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)□	5) Claim(s) is/are allowed.						
-	6) Claim(s) is/are rejected.						
	Claim(s) is/are objected to.						
8)⊠	Claim(s) <u>11-50</u> are subject to restriction and	d/or election requirement.					
Applica	tion Papers						
9)[The specification is objected to by the Exam	niner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority	under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
Č	a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received.						
	Certified copies of the priority documents have been received in Application No						
	3. Copies of the certified copies of the p		• •	Stage			
	application from the International Bur	eau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.							
Attachme	ent(s)						
	tice of References Cited (PTO-892)	· —	v Summary (PTO-413)				
3) 🔲 Info	tice of Draftsperson's Patent Drawing Review (PTO-948) ormation Disclosure Statement(s) (PTO-1449 or PTO/SB, per No(s)/Mail Date		o(s)/Mail Date f Informal Patent Application (PTC	O-152)			

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 11-26, drawn to a method of treating leukemia with cytarabine and a compound of general formula I, classified in class 514, subclass 274.
- II. Claims 27-50, drawn to compositions and combinations of cytarabine and a compound of general formula I, classified in class 514, subclass 274.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case, the composition as recited in the claims of Group II can be used in a materially different process than that claimed in the methods of Group I. For example, a composition of cytarabine and β -L-OddC could be used to treat Non-Hodgkin's lymphoma or as an antiviral.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Election of Species Requirement for Either of Groups I or II

Claims 11-20, 23-24, 27-33, 38-41, and 46-49 are generic to the following disclosed patentably distinct species: the genus of compounds represented by general formula (I) as recited in Claim 11. The species are independent or distinct because to search the entire genus of compounds would present an undue search burden on the Examiner. For example, the following compounds would be encompassed by general formula (I) as recited in the instant claims:

$$H_3C$$
 H_3C
 H_3C

Because of their structural diversity and lack of a common core, the search for Compound A would not result in identification of Compound B and *vice versa*. Thus, for purposes of examination, applicant is required under 35 U.S.C. 121 to elect a single disclosed species of Formula (I), even though this requirement is traversed.

Proper response to this election of species requirement requires that Applicant elect: A) a single disclosed compound of general formula (I) by defining the R and B substituents of said compound; and B) a single biological response modifier from the group recited in Claim 18 (or Claim 33, if applicable to elected Group).

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

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record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection

under 35 U.S.C.103(a) of the other invention.

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James D. Anderson

Examiner Art Unit 1614

May 4, 2006

ARDIN H. MARSCHEL SUPERVISORY PATENT EXAMINER